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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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09/189,415 11/10/98 FINLAY

B 07422/013001

EXAMINER

HM12/0114

LISA A HAILE
FISH & RICHARDSON
4225 EXECUTIVE SQUARE
SUITE 1400
LA JOLLA CA 92037

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| ART. 1, V | PAPER NUMBER |
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1641

DATE MAILED:

01/14/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 (one) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.
- ☐ Claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☒ Claim(s) 1-51 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice to Comply with Sequence Requirements (2 pages)
- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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DETAILED ACTION

This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c). It also does not contain a copy of the "Sequence Listing" in a computer readable form as required by 37 CFR 1.821(e). See attached form for further information.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to Tir polypeptide, classified in class 424, subclass 184.1.
- II. Claims 8-14, 36 and 37, drawn to polynucleotide, vector and host cell, classified in class 536, subclass 23.1.
- III. Claims 15-17 and 42-44, drawn to anti-tir antibody, classified in class 424, subclass 130.1.
- IV. Claims 18-22, drawn to a method of detecting tir polypeptides, classified in class 424, subclass 234.1.
- V. Claims 23-28, drawn to a method of ameliorating disease, classified in class 424, subclass 234.1.
- VI. Claims 29-32 and 45-48, drawn to a method of detecting polynucleotide, classified in class 435, subclass 7.1.

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- VII. Claims 33-35, drawn to a method of producing tir polynucleotide, classified in class 435, subclass 320.1.
- VIII. Claim 38, drawn to a method of identifying a compound that interferes with binding of a tir polypeptide to intimin, classified in class 435, subclass 4.
- IX. Claim 39, drawn to a method of differentiating among attaching and effacing pathogens, classified in class 435, subclass 4.
- X. Claim 40, drawn to a method of delivering a compound of interest to a tir-containing cell, classified in class 435, subclass 243.
- XI. Claim 41, drawn to a method of detecting cytoskeleton of a cell, classified in class 435, subclass 7.2.
- XII. Claims 49-51, drawn to a method of inducing a cell mediated immune response to a polypeptide, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups IV-XII are directed to different method with distinct procedures. For example, the method of

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Group IV is directed to detecting Tir polypeptide, whereas the method of Group VI is directed to detecting polynucleotide.

Group I and II are directed to different products which are physicochemically, structurally and functionally distinct. Furthermore, the proteins of Group I can be obtained by means other than the nucleic acid of Group II. That is, the DNA is not necessarily needed to obtain the protein; the protein can be produced synthetically. In addition, the two products have different utilities. The nucleic acid can be used in hybridization studies, whereas the protein can be used in vaccine preparations or in immunoassays.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can also be used in immunoassays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of

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their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
January 2000
Ryan/vr



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641